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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,150

08/05/2002

Gregory S. Keller

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26211 7590 11/19/2008
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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

11/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 09/980,150	Applicant(s) KELLER ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 10-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the response filed 07/21/2008.

Information Disclosure Statement

Regarding the IDS filed 10/04./2006, applicant requests that all citations be initialed. A review of this IDS shows that each one has been initialed. But to further explain, the line between initials indicates that the citation has indeed been considered without the need to actually place an initial at each location. This means, AH, AM, AN and AO have been considered. However, no citations were placed in the boxes marked AJ, AK, AQ and AR. No initial is necessary. As such, applicant's received a properly initialed and signed copy of the information disclosure statement.

The objection of claim 17 and rejection under 35 USC 112, second paragraph is withdrawn in view of applicant's cancellation of these claims.

The following rejections are maintained in this action:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1615

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansbrough et al. (JAMA 19/1989).

Hansbrough disclose the use of autologous fibroblasts in the treatment of burn wounds (see Abstract). Autologous keratinocytes are cultured at page 2125, third column, first full paragraph. The cells are cultured twice (see page 2126, first column, first full paragraph). The reference differs only in that the cultured cells are not injected, but instead either stapled or sutured as part of a composite graft. However, those of ordinary skill would expect similar wound healing results from the instant claims given the disclosure of Hansbrough et al. Barring a showing of criticality for administration through injection as opposed to any other form of administration, the instant method would have obvious given the disclosure of Hansbrough.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 197 16 098 (DE'098).

DE'098 disclose the use of autologous fibroblasts in the treatment of wounds. Cells are taken from the same tissue being treated, cultured in the subject's serum, and used to treat an epithelial wound (see 2, lines 22-25; page 4, column 17; claims 1 and 12). The instant claims are anticipated by DE'098.

Response to Arguments

Applicant's arguments filed 07/21/2008 have been fully considered but they are not persuasive.

Regarding the rejection under 35 USC 103(a) over Hansbrough et al, applicant sites the clear advantage of composites over either keratinocyte cell suspensions or keratinocyte sheets. However as stated in the rejection, those of ordinary skill would have been able to formulate any number of formulations including suspensions, given the content of the implantable sheet of Hansbrough et al. While the invention of the reference stays in place, why would one of ordinary skill not expect similar therapeutic results from taking those same cells and injecting them into the effected tissue? Many pharmaceutical or bioactive compositions can be given through various formulations. As cited in the action, what is the criticality of the suspension over the sheet of Hansbrough et al? None appears to be present. As such, the rejection under 35 USC 103(a) over Hasbrough et al is maintained in this action.

Regarding the rejection under 35 USC 102(b), applicant argues that the DE'098 reference requires the presence of a foreign gene not found in the instant invention.

Further, although there is no direct statement of culturing fibroblasts which are non-immunogenic, the reference appears to indicate culturing in the subjects serum, which would indicate this is the case. The presence of the foreign gene is not excluded from applicant's open ended claim language. As such, the rejection under 35 USC 102(b) over DE'098 is maintained in this action.

Claims 10-15 are objected to as dependent upon rejected base claims

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

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